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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,273	06/27/2005	Kostas Kosmatopoulos	260449US0XPCT	5023

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EXAMINER

BRISTOL, LYNN ANNE

ART UNIT PAPER NUMBER

1643

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/511,273	Applicant(s) KOSMATOPOULOS ET AL.	
	Examiner Lynn Bristol	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Lack of Unity Restriction*

1. Claims 1-13 are all the pending claims for this application.
2. As “use” claims, Claims 10-13 are drawn to non-statutory subject matter under U.S. practice pursuant to 35 U.S.C. 101. The claims have been withdrawn from the analysis for lack of unity and restriction requirement.
3. Claims 6-9 are in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Applicants are invited to correct the claim dependency in their response to this Action.
4. Claims 7-9 are drawn to compositions comprising at least one peptide or a polynucleotide encoding the peptide. The composition claims have been restricted into protein and polynucleotides as separate groups as discussed below.
5. Claims 1-9 are all the pending claims subject to lack of unity restriction.
6. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claims 1-9 is an MHC restricted EphA2-derived epitope(s) that induces a CTL response. In view of this, the combination of Lindberg et al (Mol. Cell Biol. 10(12):6316-6324 (1990); cited in the IDS of 10/21/2004), Parker et al. (J. of Immunol. 152:163, 1994) and Renkvist et al. (Cancer Immunol. Immunother. 50:3-15 (2001) reads on the claims.

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Lindberg teaches the cloning and amino acid sequence of EphA2, expression of the protein on epithelial cells and the overexpression of the protein associated in tumorigenesis, Parker teaches methods (BIMAS program) to identify peptides potentially capable of binding to HLA-A\*0201 and selecting those with CTL-inducing properties, and Renkvist teaches numerous tumor-associated antigens that are recognized by T cells and the HLA-restricted T-cell epitopes (peptides) associated with the antigens. Thus it would have been obvious to have obtained the EphA2 immunogenic peptides (or nucleotides encoding therefore) on the basis of the disclosures of Lindberg, Parker and Renkvist in order to facilitate the identification of the T-epitope binding domains. Therefore the technical feature recited in claims 1-9 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5 and 7-9, drawn to MHC I-restricted, EphA2-derived T-cell immunogenic peptides and compositions thereof.

Group II, claim(s) 6-9, drawn to polynucleotides encoding MHC I-restricted, EphA2-derived T-cell immunogenic peptides and compositions thereof.

7. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, in view of the teaching of Lindberg et al, Parker et al. and Renkvist et al. the groups are

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not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claims 1-9 is not special.

8. Inventions of Groups I and II represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. Group I is a peptide and Group II is a polynucleotide. The polynucleotide is different in structure from the peptide of Group I in that the polynucleotide is made up of nucleic acids and the peptide is made up of amino acids. The polynucleotide is made by nucleic acid synthesis while the peptide is made by translation of RNA or chemical peptide synthesis. The examination of all groups would require different searches in the U.S., international and foreign patent literature and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I and II are patentably distinct.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different searches in the patent literature, restriction for examination purposes as indicated is proper.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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LARRY R. HELMS, PH.D.  
SUPERVISORY PATENT EXAMINER